12 KAR 2:041. Additives.

RELATES TO: KRS 250.501, 250.511, 250.541(1)(a), (b), (c), (d), (e), (f), (j), (2)(c), (d), (e), 21 C.F.R. 570.3(1), 570.30, 582, 21 U.S.C. 151-158, 360(b)

STATUTORY AUTHORITY: KRS 250.571(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 250.571(1) authorizes the Director of the Agricultural Experiment Station to promulgate administrative regulations necessary for the efficient enforcement of KRS 250.491 to 250.631 regarding commercial feeds. KRS 250.541 provides that a commercial feed or a material exempted from the definition of commercial feed shall be considered adulterated if it meets the conditions established in KRS 250.541. KRS 250.551(1) and (2) prohibit the manufacture or distribution of an adulterated product as animal feed. This administrative regulation establishes the requirements to ensure the safe and effective use of commercial feeds containing additives.

Section 1. Before approval of a registration application or label for commercial feed containing an additive, including a drug, another special purpose additive, or nonnutritive additive, the distributor shall, upon request by the director, submit evidence to prove the safe and effective use of the commercial feed when used according to the directions furnished on the label.

Section 2. Satisfactory evidence of safe and effective use of a commercial feed shall be one (1) of the following:

(1) The use of an additive that:

(a) Conforms to the requirements of 21 CFR 570.3(1), 570.30, or Part 582; or

(b) Is considered prior sanctioned, informal review sanctioned, or generally recognized as safe (GRAS) by the Food and Drug Administration;

(2) A commercial feed that is a drug as defined in KRS 250.501(7) if it:

(a) Is generally recognized by the Food and Drug Administration as safe and effective for its labeled use according to 21 CFR 570.30 and Part 582; or

(b) Is marketed subject to an application approved by the Food and Drug Administration under 21 USC 360(b);

(3) A commercial feed used to impart immunity if the constituents have been approved for that purpose through the Federal Virus, Serum and Toxins Act, which is codified as 21 USC 151 to 158;

(4) A direct-fed microbial product if:

(a) The product is defined as a fermentation product in the Official Publication of the Association of American Feed Control Officials; and

(b) The microbial content statement:

1. Appears on the label; and

2. States "Contains a source of live (viable), naturally occurring microorganisms"; or

(5) An enzyme product if the product is:

(a) Defined as an enzyme in the Official Publication of the Association of American Feed Control Officials; and

(b) Guaranteed according to the provisions of 12 KAR 2:018.

Section 3. Incorporation by Reference. (1) "Official Publication", 1998 Edition, Association of American Feed Control Officials, is incorporated by reference.

(2) This material may be inspected, copied, or obtained at the Division of Regulatory Services, 103 Regulatory Services Building, College of Agriculture, University of Kentucky, Lexington, Kentucky 40546-0275, Monday through Friday, 8 a.m. to 4:30 p.m. (AES-2 (1973)-8; 1 Ky.R. 1000; eff. 6-11-75; Am. 23 Ky.R. 1610; eff. 1-10-97; 25 Ky.R. 1087; 2355; eff. 4-14-99.)